

Pediatric Advisory Committee Meeting
Thursday-Friday, September 22-23, 2011
Hilton Gaithersburg Hotel,
620 Perry Parkway,
Gaithersburg, Maryland, 20877

Friday, September 23, 2011

8:00 a.m.	Welcome and Introductory Remarks	Geoffrey Rosenthal, MD, PhD Chair of Pediatric Advisory Committee Director of Pediatric & Congenital Heart Center Executive Director, Critical Care Services University of Maryland Medical Center Hospital for Children Walter Ellenberg, PhD Designated Federal Official, Pediatric Advisory Committee Office of Pediatric Therapeutics, Office of Special Medical Programs, OC, FDA
8:05 a.m.	Agenda Overview	Dianne Murphy, MD, Director Office of Pediatric Therapeutics OC, FDA
8:15 a.m.	Melody Transcatheter Pulmonary Valve and Ensemble Delivery System <i>Questions</i>	Carolyn Vaughan, BSME, Mechanical Engineering Lead Reviewer, Division of Cardiovascular Devices, Office of Device Evaluation, CDRH, FDA John Sapirstein, MD, Medical Officer Division of Cardiovascular Devices, Office of Device Evaluation, CDRH, FDA Jenny Chih-Hsin Liu, RN, BSN, MSN Nurse Consultant Division of Postmarket Surveillance 1, Office of Surveillance and Biometrics, CDRH, FDA Dale Tavis, MD, MPH, Medical Officer Division of Epidemiology, Office of Surveillance and Biometrics, CDRH, FDA Susan K. Cummins, MD, MPH, FAAP Chief Pediatric Medical Officer Office of the Center Director, CDRH, FDA
9:30 a.m.	Sponsor Presentation <i>Questions</i>	Dr. Thomas Armitage, Vice President of Clinical Affairs Medtronic, Inc.
9:45 a.m.	Melody TPV <i>Questions and Recommendations</i>	Susan K. Cummins, MD, MPH, FAAP Chief Pediatric Medical Officer Office of the Center Director, CDRH, FDA

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10:00 a.m.	Abbreviated Presentations	Judith Cope, MD, MPH, Medical Officer, Office of Pediatric Therapeutics OC, FDA
	Navstel (balanced salt ophthalmic solution with hypromellose, dextrose and glutathione)	
	Akten (lidocaine hydrochloride ophthalmic Gel 3.5%)	
	Triesence (triamcinolone acetonide injectable suspension)	
	<i>Questions and Recommendations</i>	
	<u>Modified Abbreviated: rationale provided</u>	Judith Cope, MD, MPH, Medical Officer, Office of Pediatric Therapeutics OC, FDA
	Famvir (famciclovir)	
	<i>Questions and Recommendations</i>	
	Videx EC (didanosine)	
	<i>Questions and Recommendations</i>	
	Ziagen (abacavir)	
	<i>Questions and Recommendations</i>	
	Zomig Nasal Spray (zolmitriptan)	
	<i>Questions and Recommendations</i>	
10:45 a.m.	Break	
11:00 a.m.	Topamax (topiramate) Standard Review of Adverse Events	Virginia Elgin, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA
	<i>Questions and Recommendations</i>	
11:40 a.m.	Retrovir (zidovudine) Standard Review of Adverse Events	Alyson Karesh, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA
	<i>Questions</i>	
12:10 p.m.	Retrovir (zidovudine) Medication Errors Review	Carol Pamer, RPh, MS, Pharmacist/Epidemiologist Division of Medication Error Prevention and Analysis, Office of Surveillance and Epidemiology, CDER
	<i>Questions and Recommendations</i>	

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12:30 p.m. **Lunch**

1:30 p.m. **Levaquin (levofloxacin) for Anthrax Post-exposure**
Standard Review of Adverse Events

Amy Taylor, MD, Medical Officer
Pediatric & Maternal Health Staff,
Office of New Drugs, CDER, FDA

Questions and Recommendations

2:00 p.m. Open Public Hearing

3:00 p.m. **Informational Update of Kaletra (lopinavir/ritonavir)**

Debra Boxwell, PharmD, Postmarketing Safety
Evaluator, Division of Pharmacovigilance II,
Office of Surveillance and Epidemiology, CDER

Questions

3:30 p.m. **PAC Member Designated Review**

Dianne Murphy, MD, Director
Office of Pediatric Therapeutics, OC, FDA

Adjournment

4:00 p.m.

Geoffrey Rosenthal, MD, PhD
Chair of Pediatric Advisory Committee
Director of Pediatric & Congenital Heart Center
Executive Director, Critical Care Services
University of Maryland Medical Center
Hospital for Children